Supplemental materials

Template for Intervention Description and Replication (TIDieR) Checklist for the SUSHI trial intervention treatment

Item	Intervention
1. **Brief name:** Provide the name or a phrase that describes the intervention.	Help for Hands EMPOWER Programme
2. **Why:** Describe any rationale, theory, or goal of the elements essential to the intervention.	The Help for Hands EMPOWER Programme involves SaeboGlove self-directed, repetitive, functional-based practice. Rationale for this therapy: National guidelines advocate repetitive, functional-based practice and self-practice activities[1, 2]. Research shows that in order to improve brain function and regain the ability to perform every day movements after stroke, hundreds of challenging movement repetitions[3-8], specific to a given every day task[9, 10] must to be practiced. Systematic review evidence shows that after stroke 1) increased intensity of repetitive, functional-based rehabilitation is known to improve functional outcomes (dose > 20 hours)[11] and 2) self-directed interventions that involve repetitive functional-based practice can improve upper limb function and independence in activities of daily living[12]. Research on dynamic hand orthoses after stroke (including the SaeboGlove[13, 14]) consists of small feasibility studies involving between 1-20 participants with moderate and severe upper limb impairment using RCT[15-18] and non-RCT[13, 14, 19-35] designs). This preliminary evidence suggests that such devices are safe, feasible and acceptable, and enable this group to perform higher numbers of functional-based movement repetitions[13, 21, 22, 34], even when self-directed[13, 21, 22, 34]. Positive trends in upper limb recovery are observed in the acute-subacute[13, 14, 24, 32-34] and subacute-chronic[15-23, 25-31, 35] phases of recovery. Essential elements of this intervention include: • SaeboGlove device • Increased access to repetitive, functional-based practice • Increased access to self-practice opportunities • Increased intensity of training (> 100 movement repetitions daily where possible)[8]
3. **What - Materials:** Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	The **SaeboGlove** is used[36]. It consists of a glove velcroed inside a wrist splint and tensioner bands of different size/strength which span between hooks, on the SaeboGlove, over weak joints to enable variable hand opening support, essential for self-directed, repetitive, functional-based practice (Figure 1). **Hand and Arm rehabilitation exercise booklets** are used to encourage self-management[37, 38] and record active upper limb therapy time daily. Booklets provided to the intervention group will also include a paragraph highlighting the need for intensive (> 100 movement repetitions daily[8]), repetitive functional-based practice to optimise recovery, and will

	record intensity goals agreed at each review, and encourage participants to record the number of hand opening movements they perform daily during their individualised self-directed, repetitive, functional-based training programme. A **written copy of all exercises** will be provided to participants. Additionally, therapists can **video** participants performing the exercises provided on their own / their carers mobile phone / video camera if participants feel this would be helpful.
4. **What - Procedures:** Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	**Self-practice:** Intervention group participants will receive a SaeboGlove for 6 weeks to carry out self-directed, functional-based hand and arm exercises daily, independently with or without support of a carer. They will aim to fulfil a daily intensity goal agreed with their therapist (number of hand opening movements to aim to perform). **Progress reviews:** A therapist will supervise and support participants (and carers) by providing a progress review during 4 of the 6 weeks to: i) assess/reassess their ability, define/redefine their treatment plan and set shared intensity goals for their daily practice ii) administer them with an individualised self-directed, repetitive, functional-based practice training programme where all exercises provided involve grasping /releasing (where possible grasping should involve an object, alternatively it should involve opposition) iii) train them on the intervention, specifically on how to don/doff the SaeboGlove, and on how to perform any exercises given and log daily self-practice activity (number of hand opening repetitions and minutes of active practice) against their agreed goal in their booklet iv) remind them of the ultimate goal and need to increase use of their affected hand, out with therapy exercises, in everyday tasks between each review. **Rehabilitation booklet:** Site personnel will try to phone participants each week to remind them to complete their rehabilitation booklet daily. **The EMPOWER principles will be followed:** **E**quip with the tools needed to carry out meaningful exercise involving everyday tasks (e.g. eating, drinking, self-care) - a **SaeboGlove**, and **written or videoed exercises** involving everyday objects whenever possible. **M**otivate by setting shared intensity goals and logging / monitoring daily self-practice activity. Identify and overcome barriers to doing daily exercises. **P**rogress review every 1-2 weeks so exercises remain challenging and progressive. **O**ptimise self-management support at reviews by coaching independence in exercises, progression

	and tailoring. **W**ean from SaeboGlove bands and glove for some / all exercises as able. **E**ngage carer support whenever possible. **R**emind of ultimate goal and need to increase use of stroke affected hand in everyday tasks.
5. **Who provided:** For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	The intervention will be carried out by participants with support from 1) a trained therapist (physiotherapist or occupational therapist) and 2) a trained carer if needed. The therapist is a clinical specialist in stroke care, will receive training on the intervention, be provided with an accompanying therapy guidance document and observe at least one SaeboGlove Therapy session with a therapist with over 3 years' experience in the delivery of SaeboGlove Therapy. All supporting carers will be encouraged to attend review sessions with participants where they will receive training on the intervention, specifically on how to don/doff the glove, assist with the performance of any exercises and record self-practice activity. Participants and carers will be encouraged to contact their therapist for further advice if they have questions/concerns.
6. **How:** Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Typically, 1:1 face-to-face delivery, though on occasion, for participant convenience by telephone.
7. **Where:** Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	For 1:1 delivery: at bedside or clinic room in NHS hospital facilities. By telephone: in NHS hospital facilities if inpatient, or at home if discharged.
8. **When and how much:** Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Over the 6 week intervention period: • Participants will be encouraged to fulfil their individualised, shared intensity goal daily. • A progress review with a therapist will be provided every 1-2 weeks (4 occasions) at a mutually suitable time that also allows flexibility depending on anticipated rate of progress. • SaeboGlove self-directed, repetitive, functional-based practice will be in addition to usual NHS care. It is assumed that usual care is based on National Clinical Guidelines[1, 2]. Therapy teams will be asked to ensure that participants receive 45-minutes of physiotherapy and occupational therapy daily for as long as required and will be asked to record the usual care they provide on a study specific form.
9. **Tailoring:** If the intervention was planned to be	Programs will be set at 1 of 3 levels:

personalised, titrated or adapted, then describe what, why, when, and how.	**Level 1:** 1-2 exercises involving grasping / releasing (with or without wrist movement). **Level 2:** Level 1 **plus** a lower arm movement (supination/pronation or elbow flexion/extension) involving grasping / releasing. **Level 3:** Level 2 **plus** an upper arm movement (any shoulder movement) involving grasping / releasing. Participants will start at the highest level according to their ability. The difficulty level and number of exercises performed will be reduced / increased according to ability but all participants must be able to carry out at least one level 1 exercise with or without the help of a carer in order to participate in the trial. As participants move from levels 1 to 3, exercises will become progressively more difficult because each increment will involve movement of more upper limb segments and joints, and this will require greater strength to lift the weight of an increased number of body segments up against gravity[39], the ability to coordinate movement over increasing numbers of joints, and the generation of higher torque forces (T) as the length of the moment arm (r) i.e. perpendicular distance between the joint (axis) e.g. wrist, elbow, shoulder and the hand carrying a given object or force (F)) in a task is gradually increased ($T = F \times r$)[40]. Exercises selected will be functional-based movements identified as being meaningful to participants. Participants will be encouraged to learn the best way for them to achieve their daily intensity goal e.g. doing exercises all at once, or spreading exercises out separated by breaks, doing more challenging exercises first before tiring, or last after warmed up. They will also be encouraged to increase the use of their affected hand in a varying number and type of everyday tasks between each review depending on ability and preference. If the therapist feels that the SaeboGlove is no longer needed for some/all of the exercises, participants will continue to carry out an individualised self-directed, repetitive, functional-based practice training programme involving grasping/releasing based on level 3 with/without a SaeboGlove according to their changing ability. Similarly, the design of the SaeboGlove will enable assistance from tensioners to be increased / decreased according to individual ability.
10. **Modifications:** If the intervention was modified during the course of the study, describe the changes (what, why, when, and	To date there have been no modifications.

how).	
11. **How well - Planned:** If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Therapists will complete a Case Report Form after each review to document adherence at sessions. Participants will complete a Hand and Arm rehabilitation booklet to record the number of hand opening movements and minutes of self-practice they carryout daily. Data from booklets will be studied by therapists at reviews to monitor intervention adherence and take steps to optimise it.
12. **How well - Actual:** If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Unable to describe until study completion

Outcome measures

The Fugl-Meyer Upper Extremity scale (FMUE) – The FMUE[41] is a stroke-specific assessment which measures upper limb impairment using three subscales (passive range of upper limb movement and pain during passive upper limb movement (24 items, 0-48), active movement impairment (33 items, 0-66) and sensory impairment (6 items, 0-12). Each item is rated on a 3-point ordinal scale (0=cannot perform, 1=performs partially and 2=performs fully) with a higher score representing a higher performance i.e. less impairment.

Action Research Arm Test (ARAT)—The ARAT[42] measures upper limb function and dexterity in people with hemiparesis. It scores 19 items grouped into four subscales (grasp, grip, pinch and gross movements) using a 4-point ordinal scale (0-3). Items within each subscale are arranged hierarchically, such that some items may be skipped if earlier items score 0. The final score ranges from 0-57, with 57 representing the best function i.e. normal function.

A rigorous and validated approach to ARAT assessment was followed. The original ARAT by Lyle (1981) is ambiguous with little instructions for scoring[42]. Consequently, a revised standardised[43], and validated[44] version with very high inter-rater and test-retest reliability[44] was used to increase precision of scoring.

Self-Report Measures Motor Activity Log (MAL-14)—The MAL-14 [45] is a structured interview used to assess self-perceived performance (Amount of use (AOU) and quality of use (QOU)) in 14 real-world UE activities. AOU and QOU are both rated using a 6-point scale (0-5). The mean for each scale is calculated and the final score ranges from 0-5 for each scale, with 5 indicating that the affected arm is used as much (AOU) and as well (QOU) as before the stroke. There are different versions of the MAL; MAL-14, MAL-30, MAL-28, MAL-14, MAL-45, LF-MAL, Grade 4/5 MAL and Turkish, Brazilian and German versions[46]. MAL-14 will be used as it has been studied earlier after stroke, during the subacute phase[47], and has less items and therefore a smaller burden.

Stroke Impact Scale (SIS) — The SIS[48] is a two-part stroke-specific questionnaire that measures health status after stroke. Part 1 scores 59 items grouped into eight subscales (strength, hand function, ADL/IADL, mobility, communication, emotion, memory and thinking, and participation/role function) using a 5-point Likert scale. Scores for each subscale range from 0-100, with the final score for part 1 ranging from 0 to 800. The hand function and ADL/IADL are most useful for measuring health in relation to upper limb recovery. Part 2: An overall recovery score (0- 100) is also included. A higher score reflects better health in both parts.

Barthel Index (BI) – The BI[49] measures performance in activities of daily living across 10 items of activities of daily living (feeding, bathing, grooming, dressing, bowel control, bladder control, toileting, chair transfer, ambulation and stair climbing). Items are rated in terms of whether individuals can perform activities independently, with some assistance, or are dependent. Scores for each item vary between 0-1, 0-2 or 0-3 with the overall score ranging from 0-20. A higher score represents a higher performance.

The Euroquol (EQ-5D-5L™) – The EQ-5D-5L™[50] is a self-reported questionnaire for the generic measurement of health. It scores five health dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) using a five-level response (1-5, with 1 representing the best health). The responses from each dimension make a 5-digit health state profile which is combined into a single utility index value using population tariffs. An EQ-5D-5L index score of 1 represents full health.

Modified Rankin Scale (mRS) – The mRS[51] is a stroke-specific tool that measures degree of new disability/dependence after stroke using a subjective 6-point ordinal global outcome scale. Disability/dependence is rated based on an individual's independence in relation to pre-stroke activities (0=no stroke symptoms at all, 5= Severe disability due to stroke: bedridden, incontinent, and requiring constant nursing care and attention). Higher scores reflect greater disability/dependence.

Visual analogue scale for pain (VAS)[52] – A VAS is a tool often used to measure pain intensity. Individuals are asked to rate their pain intensity at a specified time (in the SUSHI trial this is the average intensity of their pain over the previous week) using an 11-point scale displayed on a 10 cm line, ranging from 0=No Pain to 10=Unbearable Pain. Higher scores reflect greater pain intensity.

All outcomes selected are widely used and accepted (FMUE[53], ARAT[53], MAL[53], SIS[54], BI[55], EQ-5D-5L[55], mRS[55], VAS[56, 57]), and have robust psychometric characteristics (FMUE[44, 58-61], ARAT[44, 60-63], MAL[45, 47], SIS[48, 64], BI[65, 66], EQ-5D-5L[67, 68], mRS[69], VAS[52, 56, 57]) in people with stroke.

However, it should be noted that while VAS is a reliable and valid measure in populations outwith stroke[70, 71], and intra-rater reliability is good in a stroke population[52], a large systematic bias has been found between raters[52]. Use of training and standardised assessment procedures have been recommended to overcome such differences[52]. Furthermore, stroke literature currently lacks a gold standard pain measure in patients with higher cortical (cognitive and visuospatial) deficits [56]. Data suggests that the validity in this group is improved using a vertical visual analogue scale [57, 72]. Thus, like all measures used, training and standardised assessment procedures will be utilised along with a training manual, a vertical scale will be used to measure upper limb pain intensity and the same assessor will assess repeated outcomes whenever possible.

Furthermore, while the MAL-14 has been found to be a reliable and valid post stroke measure[45, 47], data on the MAL is limited during the acute phase after stroke (< 1 month)[45, 47]. As SUSHI will include acute and subacute stroke patients, and acute stroke patients are likely to be inpatients with more limited opportunity to carry out everyday activities in a hospital environment, three additional upper limb activities (open a bottle or jar, tie lace, hobbies e.g. reading, cards etc) routinely accessible at a hospital beside will be scored in addition to the MAL-14 as per our pilot trial[13].

NHS and social services resource use questionnaire – The questionnaire is an adaptation of the Client Services Receipt Inventory by Beecham and Knapp (1992)[73-76]. Individuals are asked questions about the NHS and social services resources they use. This includes resources used in primary NHS care (e.g. general practice, nursing, therapy visits and prescription costs), secondary NHS care (e.g. inpatient stays and outpatient visits), social care (residential care home, nursing home and home care), and health related benefits.

Trial Management

Trial steering committee

This comprises an independent chair, two other independent members, the Chief Investigator, the co-investigator/lead physiotherapist and two other investigators. This committee shares the overall scientific responsibility of the study with the Chief Investigator and Sponsor, contributing expertise, oversight and guidance for the study duration.

Patient and carer research advisory group

This comprises two stroke survivors, two carers and the lead physiotherapist. The role of this group is to offer advice / feedback on any issues arising throughout the trial including any publications,

represent the wider views of people affected by reduced upper limb function after stroke and contribute to decision making and clinical implementation planning where relevant.

Process evaluation

The purposive sample used in the process evaluation represents more than 20% of the intervention group. Final numbers will be determined by saturation of themes (where no new themes in the data arise)[77] and resources permitting. Interviews will be designed to explore the views and experiences of participants having a stroke and receiving both usual NHS stroke rehabilitation and SaeboGlove Therapy. In order to enhance sample variation participants who provide written consent to be invited at study enrolment, will be selected to ensure representation of participants differing in age, time since stroke, severity of upper limb disability and those with and without supporting carers. Similarly, therapists will be selected to ensure representation of differing experience levels. Interviews will be conducted by a trained researcher at an agreed time and place (typically at the participants local hospital / therapists place of work), audio-recorded, and transcribed in an anonymous format. To minimise participation burden, some interviews may be carried out by telephone. Interviews will be analysed using thematic analysis[78].

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